UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

JEFFREY GRIEBEL, Plaintiff, -against- BEYOND AIR, INC., Defendant.	Case No.: 25-cv-2969-AMD-ST **AMENDED COMPLAINT** **JURY TRIAL DEMANDED**

Plaintiff Jeffrey Griebel ("Plaintiff"), by and through his attorneys, as and for his Amended Complaint against Beyond Air, Inc. ("Beyond Air" or "Defendant") hereby alleges as follows:

NATURE OF THE ACTION

1. This is an action for wrongful termination of a whistleblower who urged his employer to take action with respect to a constantly failing and dangerous medical device, which urging led to the termination of his employment and an attempt to silence him.

2. Defendant is a biopharmaceutical and critical care company that manufactures Inhaled Nitric Oxide generators (the "LungFit PH Device"). The LungFit PH Devices are used by hospitals to treat critically ill patients, including infants. The LungFit PH device has an FDA approval for newborn infants with pulmonary hypertension which has a high mortality rate if not treated rapidly.

3. In October of 2021, Defendant, impressed by Plaintiff's credentials and experience in the industry (over 25 years), hired Plaintiff for a full-time role as Director of Clinical Services. Plaintiff received nothing but reviews of "exceeds expectations" during his employment with Defendant.

4. During his employment, though, Plaintiff witnessed, and discussed with senior management and officers of Defendant, multiple hazardous and unlawful decisions by Defendant that put at risk the health of patients and clinicians at multiple hospitals, as well as that of Plaintiff's own team. These decisions included:

- Continuing to issue LungFit PH Devices to hospitals despite knowing a circuit board component overheated and melted which resulted in devices smoking in the patients' rooms (thus presenting a hazard to the patients and the clinicians operating them) without informing all customers or promptly reporting the issue to the Food and Drug Administration ("FDA");
- Continuing to issue new versions of the LungFit PH Devices that provided inaccurate nitric oxide sensor readings due to a software issue to clinicians (again without informing customers or reporting the issue to the FDA). The LungFit PH nitric oxide sensor monitors the level of inhaled nitric oxide being delivered to a patient. The LungFit PH does not have an alarm to tell the device that nitric oxide is not being generated by the internal generator, accurate readings from the sensor are the only safeguard in the event of this type of failure. All nitric oxide delivery systems contain a warning not to abruptly discontinue inhaled nitric oxide therapy which can result in patient injury or death.
- Effectively forcing hospitals to use nearly expired filters for their LungFit PH Devices and refusing to supply them with filters with a reasonable shelf life (which decision put at least one infant's life at risk); and
- Providing improperly validated accessories for the LungFit PH devices that had not gone through the proper procedures required for FDA approval to hospitals, so that Defendant could quickly offer the same product claims as its competitors.

5. Even after Plaintiff informed Defendant of the hazards of its products, Defendant continued to ignore the health risks it created, and ultimately, fired Plaintiff for speaking up literally within hours of informing Defendant that a hospital had another device failure on a patient and was requesting an investigation by Defendant.

6. Documentation recently released by a major state public university hospital system confirms and corroborates the repeated failures that Plaintiff observed in customer complaints. -- including problems with the LungFit PH Device in late 2024, immediately prior to the wrongful termination of Plaintiff. The LungFit PH Device was repeatedly found to be emitting a noxious odor; the odor was so strong that it was reported that "Fumes were strong enough to make therapists hold their breath." The latest device failure occurred on January 1st of 2025 resulting in interruption of therapy. Upon information and belief that hospital switched nitric oxide vendors in 2025.

7. Thus, Defendant has willfully violated FDA policies and procedures and retaliated against Plaintiff for addressing and refusing to comply with Defendant's reckless practices. To add insult to injury, Defendant conditioned any severance payments to Plaintiff on his signing an overly restrictive covenant effectively preventing Plaintiff from working for two years in the industry that he has worked in for over 25 years, and demanding his silence.

8. For these reasons, and as set forth more fully herein, Plaintiff seeks damages under the New York Labor Law against Defendant, including punitive damages for its willful, malicious, and wanton behavior.

THE PARTIES

9. Plaintiff is an individual residing in Brighton, Colorado.

10. Defendant is a Delaware corporation with its headquarters in Garden City, New York.

JURISDICTION AND VENUE

11. This court has jurisdiction pursuant to 28 U.S.C. § 1332 because Plaintiff and Defendant are citizens of different states and the matter in controversy exceeds the sum or value of $75,000, exclusive of interest and costs.

12. Venue is proper in this district pursuant to 28 U.S.C. §1391(b)(1) because Defendant resides in this district.

BACKGROUND

Defendant Hires Plaintiff

13. Plaintiff began working for Defendant in October of 2021, after he applied for a position as a project coordinator. At the time that he applied for a job with Defendant, Plaintiff was working as a clinical director for a spinal company. Defendant was so impressed by Plaintiff's resume (Plaintiff has a unique level of knowledge in his field and is considered an expert) and experience with inhaled nitric oxide (over 25 years both in and outside of hospitals), that Defendant created a new position specifically for Plaintiff: Director, Clinical Services.

14. As Director of Clinical Services, Plaintiff was responsible for overseeing the use of the LungFit PH Devices and communicating with hospitals. As a non-executive level employee, Plaintiff reported to senior management at Defendant. Because of his extensive experience and expertise though, Defendant did not have to train Plaintiff when he started working for Defendant, and during his employment with Defendant, Plaintiff was told he was exceeding expectations in every evaluation. Thus, there was no question that Defendant was pleased with Plaintiff's work.

Defendant Ignores Harm to Patients and Hospital Staff Caused by the LungFit PH Device

15. As Director of Defendant's clinical program, Plaintiff oversaw a number of patient incident reports concerning the LungFit PH Devices during his employment. Plaintiff sat in on biweekly calls with the engineering team that also included the CEO, COO and VP of regulatory affairs, during which the team would routinely discuss problematical issues with the device. Yet, when Plaintiff expressed his concerns about the safety of the LungFit PH Devices, Defendant denied and rejected them, to the detriment of individuals relying on and operating the machines.

16. While Plaintiff was employed by Defendant, the LungFit PH Device went through different versions of software and hardware, including the V20 Version, the V21 and 22 Versions. The V20 Version was prone to unpredictable failures, such as when a circuit board component would melt due to excessive heat, thus interrupting drug delivery, which could result in injury to patients (including the infants relying on the device). Clinicians described the signs of circuit board failure as a loud pop followed by smoke emitting from the device's shell, and one clinician even stated the smoke caused a burning sensation in their eyes.

17. At least one quarter of the devices at Defendant's largest customer failed during use, including a device used on one patient who had received a heart transplant. For example, on February 27, 2024, an employee at that hospital texted Plaintiff letting him know that "we had a device that was replaced on the 16th to fail again. It was getting real loud then had a burning plastic smell. #6 serial#[*******]. We also have #8 [*******] that supposedly couldn't pass pre-use check."

18. Practically everyone working at Defendant knew about this issue, including Beyond Air's Chief Executive Officer and Chief Operating Officer (and it was documented in Defendant's document control system). After device failures on two separate patients (considered

a "Sentinel Event"), the Respiratory Therapy Department Manager of one public hospital, at the direction of the hospital's risk management team, asked for an investigation to be performed by Defendant on the device issue. When Plaintiff brought this up to Defendant, he was ignored.

19. Yet, Defendant continued releasing the V20 Version and failed to inform its other customers of the device failure. Defendant's Chief Operating Officer, Michael Gaul, instead tried to blame the device failures on how Beyond Air's biggest customer was using the devices, but clearly this was not the case after a different hospital experienced the same issue. The LungFit PH Device subsequently failed on a patient there, leading the hospital to shut down the evaluation of the device and even send an email to Defendant about its safety concerns.

20. Upon information and belief, no documentation as to these failures was sent to the FDA, as Plaintiff never discussed filing any report with Beyond Air's Vice President of Regulatory Affairs, who would have been responsible for the same.

21. A serious issue with the V21 and V22 versions was a software issue where some of the units would randomly change a software setting which would make the nitric oxide sensor less sensitive, resulting in less reliable readings, that could substantially impact clinicians' decisions as to patient care. This was called "sensor drift."

22. Nitric oxide sensor drift was a problem with original device version released for patient use, this was known as the V19 device. A V19 LungFit PH device was used on the very first patient =and was on a low dose of nitric oxide when the nitric oxide sensor kept drifting to zero creating an alarm condition. This patient was in the intensive care unit on a heart/lung assist device, a very ill and vulnerable patient. The sensor drift occurred several times during the few hours the patient was on therapy—again no report to the FDA.

23. Due to the issue (circuit board component melting) with the V20 Version of the LungFit PH Device, a V21 Version, which included a new circuit board, was finally developed. But the same sensor drift issue continued in some of the V21 and V22 Versions, which would randomly change the software switch as mentioned in paragraph 19.

24. Due to these failures, Defendant's engineering team started to test the device. Consistent with Defendant's utter failure to address the hazardous outcomes of its decisions, on December 2, 2024, Defendant's COO, Michael Gaul, messaged a group in the office the Plaintiff was visiting, boldly stating that it had been determined the sensor drift in the V22 devices did "not pose a risk to health" and "[d]evices that exhibit this behavior can still be used clinically." Critically, the note did not explain who made such determination, how such determination was made, or whether such determination was tested.

25. On the same day, Defendant's Principal Engineer responded, reminding Gaul that "there is no customer facing documentation which discusses" the sensor drift. Upon information and belief, Gaul told the engineering team to stop testing the LungFit PH Device for sensor drift.

26. Thus, despite concerning reversions of the device to make it prone to sensor drift that gave incorrect readings for clinicians, Defendant instructed Plaintiff and other employees to continue utilizing the device and not to report any issue to the FDA or even to customers using the devices or to doctors treating patients with the device.

27. As if all of these safety concerns were not enough, Plaintiff also was concerned about other design flaws with Defendant's devices. First, the LungFit PH Device only had a low alarm (which could be set to zero) to inform patients and clinicians that no nitric oxide was being generated if the plasma chamber (which generates the nitric oxide) fails—and the plasma chamber in the LungFit PH Device has in fact failed in some devices. This design flaw is compounded

when the nitric oxide sensor drifts as described above. Defendant's CEO and COO were both aware of this issue, yet upon information and belief reported it to no one.

28. Moreover, while the LungFit PH Device has a backup system for manual ventilation with a resuscitation bag, it occasionally fails to deliver nitric oxide, due to a technical issue that Defendant knew about. Defendant chose not to add any warning to clinicians about the backup failure and how to resolve it if it occurred.

29. Plaintiff also notified Defendant on multiple occasions that the LungFit PH Device's alarm system, was not loud enough. During an evaluation at one hospital, the respiratory therapy staff refused to put a patient on nitric oxide therapy because they would not be able to hear the alarm outside of the hospital ICU room. While Defendant made improvements to the visual aspect of the alarm to make it more visible in the V20 Version, Defendant nevertheless decided not to implement a change to increase the volume because it would cost too much and delay new device builds.

Defendant Continues to Act Recklessly to Try to Stay Competitive in its Industry

30. In addition to failing to report or address serious hazards and potential harm of its devices, during Plaintiff's employment, Defendant made several other decisions regarding the LungFit PH Device and related products sold to hospitals that put patients and clinicians at risk.

31. First, Defendant ordered too many of the filters which are necessary for the LungFit PH Device to function, such that many of the filters began to expire (each has a two-year shelf life). The LungFit PH Device requires a valid, unexpired nitrogen dioxide filter to operate, and it must be changed every twelve hours during use. Instead of removing the expired filters from stock, and sending new filters to hospitals, Defendant continued sending the nearly expired filters to hospitals. This egregious conduct resulted in the transfer of an infant from one hospital to

another, because the first hospital did not have any unexpired filters it could use for the infant's therapy. Defendant even threatened to charge hospitals additional costs if they failed to return unopened expired filters to prove the filters were not used.

32. After similar situations arose where hospitals nearly ran out of filters for patient care, Plaintiff told Gaul, on multiple occasions, that Defendant should encourage hospitals to keep an emergency supply.

33. Defendant also made life-threatening decisions regarding special adapter breathing kits (the "Breathing Kits") that Defendant sells for two specific patient applications of the LungFit PH Device. LungFit PH was not able to meet hospital needs to supply fully compliant FDA approved adapter sets.

34. Rather than follow the required procedures, in order to short cut the FDA process, Defendant offered the Breathing Kits as a separate Class I item (they were supposed to be sold to customers, but were actually given out as part of a contract) with generic labeling ("Breathing Kit" 1 and 2) instead of the proper labeling for the indication with instructions for use. These Breathing kits contained parts that were very specific to two applications, Beyond Air internal staff were instructed that they could not refer to the kits based on their designed use as most competitors in the industry would do.

35. As a result, a newborn infant's therapy in one hospital was interrupted because the Breathing Kit was not properly assembled. About 6-9 months after the kits were released to customers, Defendant started the Human Factors testing that was necessary for its submission to the FDA, which Plaintiff performed. Upon information and belief, the proper kits still have not been approved by the FDA and all senior leadership at Defendant is aware of this.

36. Defendant also used other tactics to try to keep up with its competitors that Plaintiff reasonably believed were unlawful and unethical. For example, Defendant did not have its own nitric oxide system to transport patients (the LungFit PH Device was not approved for use in ambulances, planes or helicopters), although some Defendant employees were still suggesting clinicians to use them in ambulances by strapping the device down, and senior management at Defendant encouraged this), so Defendant offered hospitals a device from a different company: the AeroNOx Nitric Oxide Delivery System (the "AeroNOx System") from International Biomedical.

37. Defendant also needed to provide cylinders of nitric oxide for the transport system, but instead of using its competitor's cylinders (which it did not have access to), it attempted to use a drug compounding solution (and claimed there was a drug shortage) with drug concentrations that were not consistent with International Biomedical's recommendation or instruction. Defendant also planned to offer additional instructions to correct for the discrepancy in the cylinder concentration. Plaintiff expressed his concern about the use of these cylinders on multiple occasions, but was rebuffed. Defendant also directed field staff to "borrow" commercial nitric oxide transport cylinders from other hospitals using their connections at other hospitals that used the cylinders.

38. Defendant also attempted to skip past the need for approval of its device in Magnetic Resonance Imaging ("MRI") suites. For example, because the LungFit PH Device was not approved for use in MRI suites, Defendant directed Plaintiff's clinical team to instruct hospitals on how to set up the device outside of the MRI suite, in a way that Plaintiff believed was dangerous to his team, to clinicians using it and to patients. Yet, with willful disregard for safety, Defendant's Chief Executive Officer and Chief Commercial Officer encouraged this set up.

Independent Corroboration of the Ongoing Failures of Defendant's LungFit PH Device

39. In June 2025, a major public university health system, the university of Texas Southwestern Medical Center ("UTSW") released documentation confirming, corroborating and validating the repeated failures of the LungFit PH Device that Plaintiff was observing and reporting.

40. These dangerous incidents occurred throughout 2023 and 2024, including just before the wrongful termination of plaintiff's employment. The failures even continued into 2025 after Plaintiff's employment was wrongly terminated.

41. By way of numerous examples. UTSW reported the following frightening and dangerous incidents, with failures in at least five (5) of its twenty-one (21) devices, leading to interruption of therapy and putting patients at risk (exact dates and some information is omitted from this pleading):

- August, 2023 -- "strong burning noxious fumes detected," "fumes were strong enough to make therapists hold their breath."
- December, 2023 -- "machine began to become warm to the touch and a smell similar to burning plastic could be smelled." This occurred on a post-operative organ transplant patient.
- February, 2024 -- "The Lungfit machine (Nitric) Stopped working and stopped delivering nitric.. Machine stated main nitric failure. The machine was running real [loud] and smelled like burning plastic."
- February, 2024 [separate failure] -- "LungFit PH device's motor became very loud in patient's room with a burning plastic smell around the device."

- April, 2024 -- "RT was called to 920 by RN for LungFit making noise. Upon entering room a loud grinding noise was heard coming from the LungFit unit as well as a smell. The machine was switched off and back on to reset and appeared to be working. Then the screen went black and could not get the screen back on."
- November, 2024 -- "During Code Blue [patient experiencing life-threatening situation] Lungfit #20 malfunctioned and stopped delivering Nitric to patient several times, after resetting machine several times."
- January, 2025 -- "Lungfit gave an alarm 'Main device system failure' this morning twice while being in use on patient."

Plaintiff is Terminated for Raising Concerns About Health Risks

42. On multiple occasions during his employment, Plaintiff raised concerns as to his team's, patient, and clinician safety, based on the above hazards.

43. Specifically, Plaintiff discussed these device failures with senior management at Defendant, including Defendant's Clinical Manager, its Vice President of Regulatory Affairs, its Chief Operating Officer, and its Chief Commercial Officer. Plaintiff's concerns were largely ignored or rejected.

44. For example, when Plaintiff raised concerns about the safety of Defendant's unapproved device set up outside of MRI suites, the Chief Commercial Officer told Plaintiff that things are more lax in Europe so Defendant can use this set up there, and asked Plaintiff to create a PowerPoint presentation showing how to set up the unsafe device.

45. Finally, in December of 2024, Defendant grew tired of Plaintiff's concerns and wrongfully terminated him after he suggested a better process for addressing device failures at hospitals.

46. Plaintiff's team had to replace broken LungFit PH Devices on a December 2024 weekend in response to a request from the hospital where they were being used. Notably, all nitric oxide delivery systems contain a warning *not to* abruptly discontinue nitric oxide delivery as it can result in harm to the patient, including death.

47. After Plaintiff's team did so, Defendant's Chief Executive Officer, Steve Lisi, wrote an email to Defendant's fields teams, including Plaintiff's team, admonishing Plaintiff's team for replacing two LungFit PH Devices on a weekend after an alarm went off, because it "costs us a lot of money and is COMPLETELY UNECESSARY." He further instructed the team that in the future they should tell the hospital to keep the system and provide a replacement in 2-3 business days. Thus, Defendant's CEO discouraged Plaintiff's team from replacing a hazardous failing machine that was responsible for providing patient care on a weekend, because it was too expensive.

48. Plaintiff knew that the LungFit PH Device is used in critical care, that when it fails it can result in a life-threatening event, and that despite Mr. Lisi's assertions to the contrary, quick replacement of this particular device was necessary. Thus, on the same day, Plaintiff responded, explaining that only one device was replaced for routine maintenance. The second device was replaced because it had failed on a patient and the hospital was requesting an investigation of the device for their risk management. Plaintiff further offered to discuss the procedure for non-urgent replacement times and "come up with some reasonable guidelines" for customers and hospitals,

including hospitals operated by, affiliated with or regulated by state or local departments of an executive branch of government.

49. Yet, despite this reasonable and productive response, just one day later on December 17, 2024, Plaintiff received a call from Defendant's head of Human Relations, informing him that he was terminated. Because of Plaintiff's experience and expertise in the industry, Plaintiff's co-workers were shocked.

50. Plaintiff's termination, just one day after his response to Mr. Lisi's uneducated and unsafe demands that urgent device replacement never take place on a weekend, was plainly retaliation for his raising concerns about Defendant's unlawful practices.

51. As if wrongfully terminating Plaintiff were not enough, Defendant also provided him with a severance letter, offering only 25 days of his salary on the condition that he not work for any "Established Competitor" (Defendant provided a comprehensive list) anywhere in the United States. Plaintiff did not sign the severance letter.

FIRST CLAIM FOR RELIEF
Retaliation, New York Labor Law Section 740

52. Plaintiff repeats and realleges the preceding paragraphs of this Complaint as if fully set forth herein.

53. At all relevant times, Defendant was an "employer" and Plaintiff was an "employee" within the meaning of Section 740 of the New York Labor Law.

54. During the course of his employment with Defendant, Plaintiff raised concerns to senior management about multiple practices of Defendant that Plaintiff reasonably believed violated rules and regulations of the FDA, including failing to report malfunctions with the LungFit PH Device to the FDA and failing to follow required procedures set by the FDA as to products offered to customers.

55. Throughout his employment, Plaintiff reported these violations to senior management at Defendant. Just one day after Plaintiff expressed to senior management his intent to prepare proper guidelines to share with Defendant's hospital customers, rather than continue Defendant's desired course of action, he was terminated from his position.

56. Plaintiff was an excellent employee (and was told the same by Defendant) and thus, there was no basis for his termination, other than Defendant's wrongful retaliation against him for raising concerns to senior management and expressing his intent to inform hospitals of the problems with Defendant's practice.

57. Defendant's termination of Plaintiff for raising concerns about the health and safety of patients and hospital employees was willful, malicious and wanton.

58. For the foregoing reasons, Plaintiff seeks compensation for his lost wages, benefits and any other remuneration due and owing to him; the payment by Defendant of Plaintiff's reasonable costs, disbursements and attorneys' fees incurred in bringing this action; a civil penalty in the amount of $10,000; and payment by Defendant of punitive damages.

SECOND CLAIM FOR RELIEF
Retaliation, New York Labor Law Section 741

59. Plaintiff repeats and realleges the preceding paragraphs of this Complaint as if fully set forth herein.

60. At all relevant times, Plaintiff was an "employee" who "performs health care services for and under the control and direction of" Defendant within the meaning of Section 741(1)(a) of the New York Labor Law.

61. At all relevant times, Defendant was an "employer" which "provides health care services in a facility licensed pursuant to article twenty-eight or thirty-six of the public health law" within the meaning of Section 741(1)(b) of the New York Labor Law.

62. During the course of his employment with Defendant, Plaintiff raised concerns to senior management about multiple practices of Defendant that Plaintiff reasonably believed violated rules and regulations of the FDA, including failing to report malfunctions with the LungFit PH Device to the FDA and failing to follow required procedures set by the FDA as to products offered to customers. Defendant's practices, which violated FDA regulations and presented and continue to present a substantial and specific danger to public health and safety, the health of specific patients, as well as hospital employees, constituted "improper quality of patient care" and "improper quality of workplace safety" within the meaning of Sections 741(d), and (e) of the New York Labor Law.

63. Throughout his employment, Plaintiff reported these violations to senior management at Defendant. Just one day after Plaintiff expressed to senior management his intent to prepare proper guidelines to share with Defendant's hospital customers, rather than continue Defendant's desired course of action, he was terminated from his position.

64. Plaintiff was an excellent employee (and was told the same by Defendant) and thus, there was no basis for his termination, other than Defendant's wrongful retaliation against him for raising concerns to senior management and expressing his intent to inform hospitals of the problems with Defendant's practice.

65. Defendant's termination of Plaintiff for raising concerns about the health and safety of patients and hospital employees was willful, malicious and wanton.

66. For the foregoing reasons, Plaintiff seeks compensation for his lost wages, benefits and any other remuneration due and owing to him; the payment by Defendant of Plaintiff's reasonable costs, disbursements and attorneys' fees incurred in bringing this action; a civil penalty in the amount of $10,000; and payment by Defendant of punitive damages.

WHEREFORE, Plaintiff respectfully demands judgment in his favor and against Defendant for (i) his lost wages, benefits and any other remuneration due and owing to him in an amount to be determined at trial which is greater than $75,000; (ii) the payment by Defendant of Plaintiff's reasonable costs, disbursements and attorneys' fees incurred in bringing this action; (iii) a civil penalty in the amount of $10,000; (iv) payment by Defendant of punitive damages; and (v) such other relief as this Court deems just and proper.

JURY TRIAL DEMAND

Plaintiff demands trial by jury on issues so triable.

Dated: New York, New York
June 16, 2025

OTTERBOURG P.C.

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